IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE BENICAR (OLMESARTAN) PRODUCTS LIABILITY LITIGATION	**MDL No. 2606**
	Master Case No. 15-2606 (RBK/JS)
	Hon. Robert B. Kugler, U.S.D.J.
THIS DOCUMENT RELATES TO ALL CASES	Hon. Joel Schneider, U.S.M.J.

DEFENDANTS' BRIEF IN OPPOSITION TO PLAINTIFFS' *DAUBERT* MOTION TO EXCLUDE TESTIMONY OF DEFENSE EXPERT JERROLD TURNER, M.D.

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INTRODUCTION

Unlike plaintiffs' experts, Dr. Turner accepts the science as it exists, acknowledges its limitations, and is not willing to make unsupported leaps from incomplete data. But plaintiffs endeavor to paint Dr. Turner as a rogue "outlier" who illegitimately "rejects" the small number of studies that they claim support plaintiffs' position in this litigation. Plaintiffs' disagreements with Dr. Turner's opinions go to weight, not admissibility. Dr. Turner's opinions are the product of rigorous methods applied by a leader in the field, predicated on the "good grounds" required by *Daubert*. They should be admitted.

I. Dr. Turner Is Qualified and His Opinions Grow Out Of His Research and Experience Outside of This Litigation.

Dr. Turner has been described by plaintiffs' expert Dr. Daniel Leffler as "one of the leaders" in the pathology of gastrointestinal inflammation. Deposition of Dr. Daniel Leffler ("Leffler Dep"). at 185:7-12 (Certification of Daniel B. Carroll, Esq. ("Carroll Cert.") Ex. A). His opinions are grounded in a "broad range of knowledge, skills and training" pertaining directly to the issue presented: whether olmesartan can cause sprue-like enteropathy. *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741 (3d Cir. 1994). Plaintiffs' contentions that Dr. Turner lacks the requisite experience to offer his opinions (Motion to Exclude Dr. Jerrold Turner at 3 ("Turner Motion") (Dkt. 1076-1)) and suggestion that his opinions were "prepared solely for purposes of litigation" (*id.* at 14-15) not only are without

merit, but fly in the face of the Court's admonition to the parties to focus on methodology and not on qualifications and the like. *See In re Benicar (Olmesartan) Prods. Liab. Litig.*, Jan. 25, 2017 Transcript at 29:7-10 (Carroll Cert. Ex. B).

Dr. Turner's qualifications are top notch. He has published over 300 peer-reviewed papers on gastrointestinal symptoms, disorders, and diseases, including co-publishing on multiple occasions with Dr. Joseph Murray. *See generally* Turner Curriculum Vitae (listing publications) (Carroll Cert Ex. C); Turner Dep. at 127:5-9 (noting publication with Dr. Murray) (Carroll Cert. Ex. D). He serves as an editor on several major journals, and authored the chapter on gastrointestinal pathology in the primary textbook used in most medical schools. *See* Turner Report at 1 (summarizing leadership on relevant journals) (Plaintiffs' Certification in Support of Motion to Exclude Dr. Turner (Pls.' Turner Cert.) Ex. 2). Until his recent move from the University of Chicago to Harvard University, Dr. Turner reviewed over 1,000 gastrointestinal biopsies each year. *See* Turner Curriculum Vitae at 52 (Carroll Cert. Ex. C). Now he spends eight weeks per year dedicated to clinical pathology, and about 70% of his time on research activities. *See* Carroll Turner Dep. at 26:19-27:22 (describing current research and clinical obligations) (Cert. Ex. D). Dr. Turner is eminently qualified to opine on whether the existing science supports a causal nexus between olmesartan and sprue-like enteropathy.

Dr. Turner's opinions cannot be impugned because he had not reviewed a biopsy "where OAE was a part of a differential diagnosis" before being retained in this litigation. Turner Motion at 3 (Dkt. 1076-1); *see also id.* at 14-15. Dr. Turner need not have experience with "OAE" to render his opinions here: the Third Circuit has rejected "overly rigorous requirements of expertise" and has deemed "more generalized qualifications" sufficient. *In re Paoli*, 35 F.3d at 741. Dr. Turner cannot credibly be said to be lacking in that regard.

Dr. Turner reviewed medical literature relating to olmesartan in the course of his research and practice, including the Mayo Clinic series central to plaintiffs' claims, *before* becoming an expert in this litigation. Turner Dep. at 23:23-24:8, 25:6-16 (Carroll Cert. Ex. D). His opinions were derived through a review of substantially the same peer-reviewed literature as has been reviewed by plaintiffs' experts. *See generally* Turner Rep. (Pls.' Turner Cert. Ex. 2). And his review of those materials is informed by a lifetime of substantial work in the treatment and science of gastrointestinal disease and injury. *See supra*; *accord Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 594 (D.N.J. 2002) (a consideration concerning the reliability of methodology is whether the opinions proffered "grow[] naturally and directly out of research [he] has conducted independent of the litigation").

If plaintiffs believe that Dr. Turner's opinions are less credible because he has not encountered a case of "OAE" in practice, that is an issue for the jury and not a basis upon which to exclude his opinions. *See, e.g., Kannankeril v. Terminix Int'l, Inc.*, 128 F.3d 802, 806 (3d Cir. 1997) ("credibility decisions arise after admissibility has been determined").

II. Dr. Turner's Opinions are Well-Grounded.

Dr. Turner's opinions are rooted in "'good grounds,' based on what is known." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 590 (1993). In contrast to plaintiffs' experts, Dr. Turner acknowledged that all data have some value. But good science requires recognition of limits to existing data too. Plaintiffs criticize Dr. Turner for his unwillingness to leap from incomplete and weak scientific data to form causation conclusions. His opinions were not derived from an "unreasonably high personal standard" (Turner Motion at 4-7, 16(Dkt. 1076-1)), but rather from methods generally accepted in science and recognized by courts from around the country. On that basis, they should be admitted.

A. Dr. Turner's Opinions Are Based in Reliable Methodology.

Contrary to plaintiffs' contention (Turner Motion at 3-4, 15 (Dkt. 1076-1)), Dr. Turner's review of scientific data and methods used in forming his opinions are evident in his report. Consistent with his experience and training, Dr. Turner conducted a detailed pathological analysis of available scientific evidence

(including the cases identified in the Mayo Clinic series), reviewed the available epidemiology and controlled studies, and considered case reports. *See* Turner Rep. at 2-8 (Pls.' Turner Cert. Ex. 2). Dr. Turner assessed substantially the same peer-reviewed literature reviewed by plaintiffs' experts in forming their opinions. *See id.* His methodology meets the standard for admissible expert opinion set forth in Rule 702 and *Daubert*. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999) (experts must "employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field").

Courts in this Circuit recognize that all data are not created equal. *See, e.g., Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434, 457-58, 532-44 (W.D. Pa. 2003) (delineating between the quality of case reports versus epidemiology for proof of causation). Dr. Turner's opinions are not derived from an "unreasonably high personal standard." Turner Motion at 4-7 (Dkt. 1076-1). In line with the well-recognized hierarchy of medical evidence, Dr. Turner opined on the manner in which general causation can be proven, and concluded that the existing science is lacking:

> Q: What would you like to do to prove this? What you like to see somebody actually structure a randomized controlled trial to study this question?
>
> A: You could do that. You could do animal studies. You could do case control studies. You could do controlled dechallenge/rechallenge. None of it has been done – well, some

> of it has been done. To the extent it's been done, none of it has shown a clear causation.

Turner Dep. at 216:6-17 (Carroll Cert. Ex. D); *accord* FJC, Reference Manual on Scientific Evidence at 723-24 (3d ed. 2011) (describing the hierarchy of medical evidence). Requiring reliable data before declaring a causal nexus between a drug and effect is not "unreasonable"; it is good science.

Dr. Turner's opinions reflect a thorough evaluation of the existing literature. Publications supporting an association between olmesartan and sprue-like enteropathy are largely unreliable case reports and case series. *See* Turner Rep. at 2-6 (Pls.' Turner Cert. Ex. 2). Those include the reports of uncontrolled positive rechallenges that plaintiffs tout. *See, e.g.,* Turner Motion at 5-6 (Dkt. 1076-1); Turner Dep. at 74:13-16 (noting the absence of controlled rechallenges in case reports) (Carroll Cert. Ex. D); *id.* at 104:7-110:13 (discussing report of an uncontrolled positive rechallenge). As noted *infra* at 8 and elsewhere, courts around the country have found such data unreliable bases upon which to render opinions on causation. *See also* Turner Dep. at 215:4-216:1 (testifying that case reports do not produce reliable information for causation opinions) (Carroll Cert. Ex. D). Studies traditionally considered to produce more reliable data – epidemiological and case controlled studies – have almost uniformly found no drug effect. *See* Turner Rep. at 6-7 (Pls.' Turner Cert. Ex. 2).

In light of the existing literature, Dr. Turner's opinions are not "unreasonable." For example, plaintiffs contend that requiring a controlled rechallenge is too stringent a standard. *See* Turner Motion at 5, 16 (Dkt. 1076-1). But controlled rechallenges – as opposed to the uncontrolled rechallenges found in the case reports that plaintiffs trumpet – eliminate the risk of a placebo effect and allow for the scientific evaluation of the variables affecting a particular patient:

> Q: The reason that you say a blinded controlled rechallenge is for what reason? Why do you use that as your standard?
>
> A: Because we know that the placebo effect is very strong, and that it's been demonstrated in study after study. And so if you tell a patient now I'm going to give you olmesartan, let's see if things recur, and the patient in their mind is believing that olmesartan caused that, without intentionally lying or other intended deceit, the patient may experience those symptoms.

Turner Dep. at 120:18-121:5 (Carroll Cert. Ex. D); *see also id.* at 304:17-305:24 (differentiating between controlled and uncontrolled rechallenges). Dr. Turner's preference for controls is not "unreasonable" – it is an effort to ensure unbiased validation of reported drug effects.

That some courts in certain cases have found that causation can be established without epidemiological or controlled studies (Turner Motion at 16 (Dkt. 1076-1)) does not mean that Dr. Turner's evaluation of the available science was methodologically unsound. Similarly, though the absence of a causal mechanism as defined in the medical literature does not preclude causation (Turner

Motion at 9 (Dkt. 1076-1)), that void in science weakens the case – it is not a flaw in Dr. Turner's methodology. *See, e.g.,* Turner Rep. at 8 (Pls.' Turner Cert. Ex. 2). And plaintiffs' proclamation that Dr. Turner's opinion is an "outlier" is dependent on the hollow supposition that there is a "scientific consensus" that olmesartan causes sprue-like enteropathy. *See, e.g.,* Brief in Support of Motion to Exclude Testimony of Dr. Leffler and Dr. Benjamin Lebwohl at 15-25 (discussing studies) (Dkt. 1066-1) . If plaintiffs disagree with Dr. Turner's analysis of existing data, they can cross-examine him in front of a jury. *See, e.g., Kannankeril*, 128 F.3d at 806. Notwithstanding, plaintiffs take issue with Dr. Turner's assessment (or lack of an assessment) of particular information:

Case Reports. Like courts around the country, Dr. Turner concluded that case reports do not provide reliable evidence of causation. *See, e.g., Brumbaugh v. Sandoz Pharm. Corp.*, 77 F. Supp. 2d 1153, 1156 (D. Mont. 1999) ("Neither case reports nor adverse drug reaction reports contain scientific analysis with the safeguards of a controlled experiment. . . . [T]hey reflect reported data, not scientific methodology"); *Soldo*, 244 F. Supp. 2d at 465 (same); *Okuda v. Wyeth*, No. 1:04-cv-80 DN, 2012 WL 12337860, at * 2 (D. Utah, July 24, 2012) (same) (Defendants' Certification in Support of Motion to Exclude Dr. David A. Kessler ("Dfs.' Kessler Cert."), Ex. P). He did not "reject" or "refus[e] to consider" case report data (Turner Motion at 5-7, 16 (Dkt. 1076-1)); he recognized their

appropriate limits. *See, e.g.,* Turner Dep. at 48:20-49:17 (case reports may show "a correlation" but are "wholly uncontrolled" and contain "no data really supporting causation") (Carroll Cert. Ex. D); *id.* at 268:11-269:23 (testifying that he formed his opinions based on all available data: "Everything that you can find, all data that are available should be considered, and these data [case reports] should be under that umbrella"). His assessment of case reports was consistent with the hierarchy of scientific evidence and prevailing case law.

The ROADMAP and Greywoode Studies. Whether or not the ROADMAP and Greywoode studies are "underpowered" (Turner Motion at 7-8 (Dkt. 1076-1)), both developed data sufficient to make statistical observations relating to the effects of olmesartan on the gastrointestinal system. *See* J. Menne et al., "Olmesartan and Intestinal Adverse Effects in the ROADMAP Study," *Mayo Clin. Proc.* at 1230-1232 (December 2012)(Defendants' Certification in Support of Motion to Exclude Susan Hutfless, Ph.D. ("Pls.' Hutfless Cert.") Ex. Y); R. Greywoode et al., "Olmesartan, other anti-hypertensives, and chronic diarrhea among patients undergoing endoscopic procedures; a case control study," *Mayo Clin. Proc.* at 1239-1243 (Sept. 2014) (Dfs.' Hutfless Cert. Ex. T). Data from these studies showed no drug effect. *See id.* As Dr. Turner testified, "if we're going to use a low bar of how we pile things up, then the Greywoode study certainly" supports a conclusion that olmesartan does not cause sprue-like

enteropathy; "It's at least as good as the case reports." Turner Dep. at 257:13-19 (Carroll Cert. Ex. D). No less can be said for the ROADMAP study data.

Dr. Turner's valuation of the Greywoode and ROADMAP data – data from two epidemiological studies – is consistent with the hierarchy of scientific evidence. Dr. Turner did not elevate a single case report from the ROADMAP study over the statistical observations, but that determination is hardly a methodological shortcoming (Turner Motion at 7-8 (Dkt. 1076-1)). *Accord Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1316 (11th Cir. 1999) ("While we acknowledge the importance of anecdotal studies for raising questions and comparing clinicians' findings, in the face of controlled, population-based epidemiological studies which find otherwise, these case reports pale in comparison"). Dr. Turner's assessment of the Greywoode and ROADMAP studies was methodologically sound.

The Basson Study. Dr. Turner did not "reject" the Basson study. *See* Turner Motion at 8-9 (Dkt. 1076-1). Rather, he observed that the study had limitations. Specifically, Dr. Turner noted that the study produced a grossly false positive result when it found almost a five-fold increase in the association of celiac disease and olmesartan – something even plaintiffs concede there is no science to support. *See* Turner Rep. at 6 (Pls.' Turner Cert. Ex. 2); *accord, e.g.,* Leffler Dep. at 25:6-26:9 ("So olmesartan does not cause – we do not believe causes celiac

disease") (Carroll Cert. Ex. A). Further, Dr. Turner observed that malabsorption, used to associate olmesartan and sprue-like enteropathy in the Basson study, is not an accurate surrogate for sprue-like enteropathy. *See* Turner Rep. at 6 (Pls.' Turner Cert. Ex. 2). Accordingly, Dr. Turner concluded that "while the French study has value, it is imperfect and is not reproducible in three other data sets" from other studies "that included American and international patients." *Id.* If plaintiffs disagree with Dr. Turner's conclusions regarding the value of the Basson study, that is an issue of weight and not admissibility. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) (the standard for admissibility centers "on principles and methodology, not on the conclusions that they generate").

Internal Company Documents. Dr. Turner's "failure" to review internal Daiichi Sankyo documents is not a methodological flaw. *See* Turner Motion at 4 (Dkt. 1076-1). Indeed, as this Court has found, the internal documents on which plaintiffs have focused to support general causation do not provide such proofs. *See In re Benicar (Olmesartan) Prods. Liab. Litig.*, No. 15-2606, 2016 WL 6652358 at *3-*8 (D.N.J. Nov. 8, 2016) (Carroll Cert. Ex. E). Scientists need not review company documents to render informed and reliable opinions on causation, and the election not to review those materials goes to the weight of Dr. Turner's opinions and not their admissibility. *See In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 427 (S.D.N.Y. 2016) ("Defendants' experts' failure to confront

alleged conflicting statements made by Bayer does not warrant exclusion under *Daubert*"); *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 735 (S.D. W.Va. 2014) (expert's "failure to review particular [internal] documents" that purportedly "refute his conclusion" "goes to the weight of his opinion, not its admissibility").

Nonetheless, plaintiffs claim that Dr. Turner may have changed his opinion had he reviewed those documents. *See* Dkt. 1076-1 at 4. But plaintiffs mischaracterize Dr. Turner's testimony. Dr. Turner testified that internal company documents "wouldn't be the only factor in my thinking, because I would be just accepting their conclusion . . . it would really depend on why they were making that conclusion." Turner Dep. at 94:5-19 (Carroll Cert. Ex. D). The "why" is critical: what plaintiffs suggest Dr. Turner should have reviewed are documents pertaining to adverse event reports and individual case assessments (*see* Turner Motion at 4 (Dkt. 1076-1), which Dr. Turner repeatedly opined (and courts have found (*see supra* at 8)) are not reliable evidence of causation. *See, e.g.,* Turner Dep. at 48:20-49:7 (Carroll Cert. Ex. D); Pls.' Turner Rep. at 2-6 (Turner Cert. Ex. 2); *see also supra* at 8. Dr. Turner's opinions rest on a thorough assessment of peer-reviewed literature concerning olmesartan, and comport with the requirements of Rule 702. *See* Fed. R. Evid. 702(b) (expert opinion must be "based on sufficient facts and data").

* * *

Dr. Turner need not identify a publication affirmatively disproving a causal connection between olmesartan and sprue-like enteropathy to render a reliable opinion that the science does not support such a connection. *See* Turner Motion at 2 (Dkt. 1076-1). The scientific method does not set out to prove a negative; the absence of support allows for a negative inference. *See, e.g.,* Turner Dep. at 58:11-59:5 (Carroll Cert. Ex. D). Dr. Turner conducted a detailed analysis of available peer-reviewed data. Based on his vast experience and training, and application of methods he uses every day in practice, he concluded that the science does not support a causal nexus. Dr. Turner was unwilling to fill gaps in science by making the same sort of unsupported leaps made by plaintiffs' experts. *Accord In re Propulsid Prods. Liab. Litig.*, 261 F. Supp. 2d 603, 615 (E.D. La. 2003) (the judicial process "must function in the present assessing evidence that presently exists"). If plaintiffs disagree with Dr. Turner's opinions, that is an issue of weight and not one of admissibility. *See Gen. Elec.*, 522 U.S. at 146. His opinions should be admitted.

B. Dr. Turner's Opinions Are Not Internally Inconsistent.

Plaintiffs repeatedly blur the lines between distinct opinions to contend that Dr. Turner's opinions are internally inconsistent. Turner Motion at 15-16 (Dkt. 1076-1). But these contentions go to Dr. Turner's credibility as a witness and the weight of his testimony, not to the admissibility of his opinions. *See, e.g.,*

Kannankeril, 128 F.3d at 806. Moreover, as set forth below, plaintiffs' contentions fundamentally misconstrue Dr. Turner's opinions. Dr. Turner's opinions and methods are entirely consistent.

Clinical Practice v. Causation. Dr. Turner believes that there is some value even in imperfect and unreliable data. Accordingly, he opined that it may be reasonable for a clinician to act on data from the existing science relating to olmesartan. *See, e.g.,* Turner Dep. at 300:12-301:13 (Carroll Cert. Ex. D). Contrary to plaintiffs' contention (Turner Motion at 6-7, 10-11 (Dkt. 1076-1), however, his acknowledgement that clinicians treat patients based on the information available, and may stop olmesartan based on that information, is not tantamount to an opinion that the available data establishes a causal nexus between drug and effect. As Dr. Turner explained, resolution of symptoms upon dechallenge constitutes only anecdotal evidence of a correlation between olmesartan and the resolved effect, not evidence of causation. *See id.* at 115:16-119:17 (distinguishing between anecdotal case data and reliable causation evidence).

In other words, Dr. Turner is not willing to do what plaintiffs' experts have done: equate clinical decision-making with scientific evaluation, and extrapolate from existing unreliable data to opine that olmesartan causes sprue-like enteropathy. This is mainstream methodology grounded in the hierarchy of

scientific evidence (*see supra* at 8), not an "outlier" opinion. *See* Turner Motion at 2-3 (Dkt. 1076-1). "We disagreed on whether they [case reports] prove causation. I don't think they're completely useless studies, they are of interest, they do bring people's attention to things." *Id.* at 281:19-23; *accord* 134:17-135:7 (clinical judgment cannot be substituted for scientific evaluation). Dr. Turner's opinion that clinicians can use existing data to treat patients is not at odds with his opinion that the scientific data does not support causation. *Accord Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1205-07 (8th Cir. 2000) (delineating between inexpert opinion "concerned with identifying and treating [the plaintiff's] condition" and opinion seeking to "identify[] the specific substance that caused [the plaintiff's] condition").

Regulatory Pronouncements v. Causation. As set forth in defendant's motion to exclude plaintiffs' expert Dr. David Kessler, FDA conclusions have a regulatory purpose that cannot be reliably translated to medical/scientific causation. *See* Memorandum in Support of Defendant's Motion to Exclude the Opinions of Dr. Kessler ("Kessler Memo.") at 3-8 (Dkt. 1065-1). Dr. Turner's acknowledgement of the language of the FDA's July 2013 safety alert is of no moment. *See* Turner Motion at 9-10 (Dkt. 1076-1).

As a preliminary matter, the FDA's determinations as a public health organization serve a fundamentally different purpose than scientific determinations

relating to the causal nexus between a drug and effects. *See* Kessler Memo. at 3-8 (Dkt. 1065-1). Accordingly, Dr. Turner can agree with a regulatory undertaking without agreeing that the science supports the substance of it. Moreover, as Dr. Turner testified, "I think they're [the FDA] using the regulatory phraseology, so they're saying 'can' as in it's possible that they [the drugs] caused these intestinal problems." Turner Dep. at 98:8-99:2 (Carroll Cert. Ex. D). Dr. Turner does not reject the possibility that, some day, science may substantiate a causal nexus. *See id.* at 279:9-23. But it does not now in Dr. Turner's opinion (*see supra* at 6-7), and any arguable tension between Dr. Turner's evaluation of the existing science and the FDA's regulatory expression concerning olmesartan is a matter that can be aired in cross-examination before a jury. *See, e.g., Kannankeril*, 128 F.3d at 806.

* * *

Dr. Turner's opinions were wrought through a critical review of existing scientific data. His appreciation of the differences between clinical practice, regulatory function, and scientific evaluation reflect his extraordinary experience and work in the area of gastrointestinal medicine. His opinions meet the requirements of Rule 702 and *Daubert*, and are not internally inconsistent.

CONCLUSION

For the foregoing reasons, Plaintiffs' Motion to Preclude Opinions of Defense Expert Jerrold Turner, M.D. (Dkt. 1076) should be denied, and Dr. Turner should be permitted to express the opinions proffered by defendant in this litigation.

Respectfully submitted,

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